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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/628,401	08/01/2000	Kenneth Kensey	V1025/20044	5645

7590

09/11/2002

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EXAMINER

WINGOOD, PAMELA LYNN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 09/11/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/628,401

Applicant(s)
Kensey et al.

Examiner
Pamela Wingood

Art Unit
3736



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 6.24.02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 28-41, and 43-56 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33-41 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-6, 11-13, 15, 16, 43, 45, 48, 51, 54, and 55 is/are rejected.
- 7) ☒ Claim(s) 3, 7-10, 14, 28-32, 44, 46, 47, 49, 50, 52, 53, and 56 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4, 7-8 6) ☐ Other:

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DETAILED ACTION

Examiner appreciates the election of the Group 1 Claims, accordingly, the restriction requirement is hereby made final and the non-election claims are withdrawn from consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 11 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Solar .

Solar discloses a vibrating tip catheter which is inserted into the body and vibrated at varying amplitudes and frequencies (Col. 6, lns. 7-12) to enhance the ability of catheters and guidewires to effectively cross lesions or stenosis. It is inherent that the vibratory energy imparted to the blood would provide the beneficial effect of changing the viscosity to enable passage of the catheter.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Braun , Sr. et al. in view of Kron.

Braun, Sr. et al. discloses a device and method for measuring the effects of anti-coagulants, medicines and titrations on the viscosity of the blood of a person in order to determining the effect of the agent on the viscosity of the blood (Col. 5, lns. 35-40); however, it does not conduct the test in vivo.

Kron discloses a device for measuring the viscosity of the blood in vivo in an analogous art for the purpose of determining the measuring the property of fresh blood.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device of Braun, Sr. et al as shown by Kron because the in vivo testing would ensure that the blood was immediately tested and fresh to avoid any coagulation or significant alteration in the physicochemical properties that would be caused by stored blood. (Col. 1, lns. 10-20).

5. Claims 1-2, 43, 45 and 54-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kron et al. in view of Kron.

Kron et al. discloses a device and method having an analyzer to determining the viscosity of the beings blood at plural shear rates (Col. 6, lns. 1- 60) at a wide range of values (See Table

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1); however, it does not have a portion of the device coupled to the being to measure the viscosity.

Kron discloses a device for measuring the viscosity of blood having a needle to be inserted into the vein in an analogous art for the purpose of obtaining fresh blood from immediately within the vasculature. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the device of Kron et al. as shown by Kron because the invivo measurement would produce the most accurate results before any physicochemical alterations occur. (Col. 1, lns. 40-52).

6. Claims 12-13,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solar in view of Braun, Sr. and Kron.

Solar discloses a vibrating tip catheter which is inserted into the body and vibrated at varying amplitudes and frequencies (Col. 6, lns. 7-12) to enhance the ability of catheters and guidewires to effectively cross lesions or stenosis. It is inherent that the vibratory energy imparted to the blood would provide the beneficial effect of changing the viscosity to enable passage of the catheter; however, it does not disclose the use of drugs to increase viscosity. determining the effect of the agent on the viscosity of the blood (Col. 5, lns. 35-40).

Braun, Sr. and Kron discloses a device and use of drugs for enhancing viscosity and for measuring the viscosity of the blood in vivo in an analogous art for the purpose of determining properties of fresh blood.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the device Solar in view of Braun, Sr. et al as shown by Kron because the in vivo testing would ensure that the blood was immediately tested and fresh to avoid any coagulation or significant alteration in the physicochemical properties that would be caused by stored blood. (Col. 1, lns. 10-20).

7. Claims 48 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieseewetter et al. in view of Kron.

Kieseewetter et al. discloses a device for determining the viscosity of blood and plasma having a column for fluid (36 at Fig. 4), a viscosity calculation means (Col. 7), fluid from the patient is to be inserted into (36), and a sensing means for monitoring the height of the column of fluid using sensors and calculation means (Col. 6, lns. 1-40 and Col. 9, 44-69 and Col. 10, lines 1-17); and has associated software to effect the computations; however, it does not have means to insert the capillary tube into to vasculature.

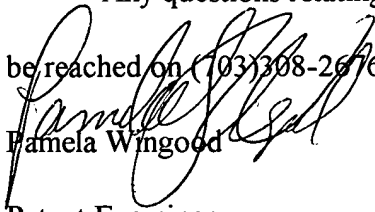
Kron discloses a device for measuring the viscosity of blood having a needle to be inserted into the vein in an analogous art for the purpose of obtaining fresh blood from immediately within the vasculature. It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have modified the device of Kieseewetter et al. as shown by Kron because the invivo measurement would produce the most accurate results before any physicochemical alterations occur. (Col. 1, lns. 40-52).

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Allowable Subject Matter

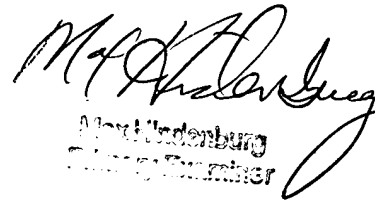
8. Claims 33-41 are allowed.
9. Claims 3, 7-10, 14, 28-32, 44, 46-47, 49-50, 52,53 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any questions relating to this application can be addressed to Pamela Wingood who can be reached on (703)308-2676.


Pamela Wingood

Patent Examiner

September 9, 2002


Albert Hadenburg
Patent Examiner